Ideas do not turn into products without the intervention of many different types of experts. Medical devices, drugs and diagnostics are particularly hard to turn into products because they are highly regulated and require disciplined adherence to quality systems. In this course, we follow the progress of products through the identification of intellectual property, the animal and clinical trials to establish safety and efficacy, the gradual refinement of the product composition and quality specifications to the final goal of commercialization. You will be exposed to many types of activities, some of which may help you to define if further study or career development is right for you. You will see how business concepts merge with project management and science in order to make and keep products safe and saleable. A more detailed agenda for the course will be posted on Blackboard before the course starts, to specify the content of the lectures for each day of the class. A field trip is also planned so that some of the concepts discussed in class can be seen in practice.
Objectives

After completing this course, you should be able to:

- Describe the typical structure and goals of different departments in a biomedical business, and recognize when individuals from these departments should be involved in decisions about medical product development
- Understand intellectual property rules sufficiently to read a patent effectively, write an invention disclosure and review the patent literature without assistance
- Show how to find the classification of a product in the DA database system, and to connect that classification with appropriate regulations
- Identify the types of safety and efficacy testing that must be applied to implantable devices and drugs prior to use in humans
- Apply design controls to new product development
- Describe how to design and manage a simple clinical trial under Investigational Exemption rules
- Develop a rudimentary qualification test plan for a new product based on a faults and hazards analysis
- Describe the basic principles and components of a quality assurance program
- Demonstrate how to implement and maintain standard operating procedures, travelers, and inspection reports.
- Be able to produce an advertisement that does not contravene FDA rules
- Understand and avoid potential ethical and legal liability problems

Assignments and Grading

Typical Assignments

Project 1: Clinical Trial Design: You will be asked to critique a clinical study with an emphasis on its design and statistical analysis.

Project 2: Patent Analysis: You can pick any medical product in which you might be interested (hint: pick something that you may be considering for your Project 3 topic). Find a few of the most relevant patents and explain what licenses you might need to make and sell a competing or improved product.

Project 3: New Product Development: You will work as a team to determine the feasibility of a new product. The team will have subgroups to deal with specific aspects of product development, for example:
  - Market Requirements and Reimbursement Strategy
  - Design, Technology and Safety Issues
  - Regulatory and Clinical Trials Strategy

Each team will be evaluated on its oral presentation and written report of no more than about 30 pages. The report from each subgroup can include any supporting documentation deemed important, but it will be graded primarily on the coherence of a one page Executive Summary of that aspect of product development plus an Executive Summary from the whole team about the proposed product. There should also be a brief statement from the team listing the individual contributions of each member. One or more members from each team may present as long as the total time does not exceed the time allotted for the team.
Grading

Marks will be based on three class projects, one midterm examination and a final examination. The breakdown of marks is as follows:

- Class Quizzes (best 8/10) 10%
- Class project 1 10%
- Class project 2 10%
- Class project 3 Report 10%
- Presentation 20%
- Midterm examination 10%
- Final examination 30%

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100%

Delays in submitting reports will be tolerated only if special circumstances exist and permission is given before the deadline. Otherwise marks will be subtracted at a rate of 5% per day.

There will be a brief quiz at the beginning of every class covering the assigned readings. This is to assure that everyone is prepared for a useful discussion. Only the best 9 of 12 such quizzes will be counted, so there should be no problem if you miss a class and have to watch the recording later on the video captured and held on Blackboard. The midterm exam will deal with material presented in the prior lectures so that students can calibrate their performance and study methods early in the course. The final exam will test on all aspects of the course and on the ability to integrate knowledge to solve realistic problems.

Course Readings


Clinical Evaluation of Medical Devices, Becker & Whyte, eds., Humana Press, 2006, posted electronically

Course Plan and Outline

The course plan is built around three-hour sessions designed to introduce you to different aspects of product invention and development. We will use case studies, group projects and bring experts to the classroom so that you can see how different experts work together. We will emphasize projects that cut across different areas of development and help you to develop your team work capabilities.
<table>
<thead>
<tr>
<th>Session</th>
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Statement on Academic Conduct and Support Systems

Academic Conduct
Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Section 11, Behavior Violating University Standards https://scampus.usc.edu/1100-behavior-violating-university-standards-and-appropriate-sanctions. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on scientific misconduct, http://policy.usc.edu/scientific-misconduct.

Discrimination, sexual assault, and harassment are not tolerated by the university. You are encouraged to report any incidents to the Office of Equity and Diversity http://equity.usc.edu or to the Department of Public Safety http://capsnet.usc.edu/department/department-public-safety/online-forms/contact-us. This is important for the safety of the whole USC community. Another member of the university community – such as a friend, classmate, advisor, or faculty member – can help initiate the report, or can initiate the report on behalf of another person. The Center for Women and Men http://www.usc.edu/student-affairs/cwm/ provides 24/7 confidential support, and the sexual assault resource center webpage http://sarc.usc.edu describes reporting options and other resources.

Support Systems
A number of USC’s schools provide support for students who need help with scholarly writing. Check with your advisor or program staff to find out more. Students whose primary language is not English should check with the American Language Institute http://dornsife.usc.edu/ali, which sponsors courses and workshops specifically for international graduate students. The Office of Disability Services and Programs http://sait.usc.edu/academicsupport/centerprograms/dsp/home_index.html provides certification for students with disabilities and helps arrange the relevant accommodations. If an officially declared emergency makes travel to campus infeasible, USC Emergency Information http://emergency.usc.edu will provide safety and other updates, including ways in which instruction will be continued by means of blackboard, teleconferencing, and other technology.

Emergency Preparedness/Course Continuity:
In case of emergency, and travel to campus is difficult, USC executive leadership will announce an electronic way for instructors to teach students in their residence halls or homes using a combination of Blackboard, teleconferencing, and other technologies. Instructors should be prepared to assign students a "Plan B" project that can be completed at a distance. For additional information about maintaining your classes in an emergency please access: http://cst.usc.edu/services/emergencyprep.html